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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/633,238	08/01/2003	Tilak M. Shah	4179-126	2458

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INTELLECTUAL PROPERTY / TECHNOLOGY LAW  
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EXAMINER

FIDEI, DAVID

ART UNIT PAPER NUMBER

3728

DATE MAILED: 03/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/633,238

Applicant(s)

SHAH, TILAK M.

Examiner

David T. Fidei

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 22-42 is/are pending in the application.
- 4a) Of the above claim(s) 30 and 39-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22-29 and 31-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 27, 2006 has been entered.

2. Newly submitted claims 30, 39 and 40-42 directed to an invention that is independent or distinct from the invention previously claimed for the following reasons:

The kit claims were previously restricted, see the Action Mailed April 14, 2005

Claims 40-42 appear to be directed to the method of using the previously claimed tube in a analytical method. The tube previously claimed can be used in a different method such as one that does not involve inserting the tube into a centrifuge, flattening the tube or providing a swab.

Applicants cannot file an RCE to obtain continued examination on the basis of claims that are independent and distinct from the claims previously claimed and examined as a matter of right (i.e., applicant cannot switch inventions). See 37 CFR 1.145. Any newly submitted claims that are directed to an invention that is independent and distinct from the invention previously claimed will be withdrawn from consideration and not entered, see M.P.E.P. 706.07 (h).

Accordingly, these claims have been withdrawn from consideration and should be cancelled to be considered responsive to this Office Action.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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4. Claims 22-29 and 31-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Nothing in the present specification describes a body that has a substantially uniform diameter along the open proximal end. Also nothing is set forth regarding the centrifuge tube of body with an average cross-sectional area in a direction perpendicular to the central axis, and the open proximal end has a cross-sectional area at least as large as the average cross-sectional area.

The Examiner's reviewing authority has commented on remand that speculating parameters from the drawings is inappropriate when the disclosure must describe the claimed invention with all its limitations, citing Tronzon v. Biomet Inc., (Fed. Cir. 1998); Lockwood v. American Airlines Inc., (Fed. Cir. 1997).

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 22-24, 26-29, 31-33 and 35-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tobler (Patent no. 5,255,808). A tubular member 2 is disclosed in figure 2 having a closed distal end at 3 and an open proximal end at 5, with integral hinge elements 6 at opposing sides thereof for facilitating flattening of the tube. The difference between the claimed subject matter and the body is recited to have a "uniform" diameter along the open proximal end.

The particular shape of the body proximal end, uniform, non-uniform or a cross section at least as large as the average cross section fails to solve any stated problem or is for any particular purpose. In fact nowhere in the present disclosure does applicant explicitly set forth a uniform diameter along the open proximal end. Accordingly, it would have been obvious and well within the level of ordinary skill in the art to construct the distal end uniform, for the reason that such a change would have merely been a matter of design choice.

As to claim 26, Tobler discloses a tube comprising folding lines 6 on an exterior surface of the tube, that also constitute a ridge structure.

As to claims 27 and 36, process by which the tube is formed, i.e., by a molding technique selected from the group consisting of extrusion blow molding and rotational molding, is not seen as imparting a distinguishing characteristic over the product per se.

As to claims 28 and 37, it would have been a matter of ordinary skill to construct the generally cylindrical form about 3 to 8 inches, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237 (CCPA 1955). Also, it has been held that where the only difference between the prior art device and the claimed device was a recitation of relative dimensions, the claimed device was not patentably distinct from the prior art device, *Gardner v. TED Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. Denied, 469 U.S. 830, 2325 USPQ 232 (1984), see M.P.E.P. 2144.04 (IV).

As to claims 29 and 38, polypropylene is disclosed in col. 6, line 16 of Tobler.

8. Claims 25 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tobler as applied above, and further in view of Amand (U.S. Patent no. 3,537,498). Tobler (Patent no. 5,255,808) discloses the claimed subject matter except for a concave depression on

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an exterior surface facing one another. Amand teaches a concave depression on an exterior surface facing one another as shown in figure 1 by sections 2, 3. It would have been obvious to one of ordinary skill in the art to modify the containers of the prior art by constructing such a feature. The motivation for this modification is permit grasping thereof.

**REPLY BY APPLICANT OR PATENT OWNER TO THIS OFFICE ACTION**

9. “In order to be entitled to reconsideration or further examination, the applicant or patent owner must reply to every ground of objection and rejection in this Office action. The reply must present arguments pointing out the specific distinctions believed to render the claims, including any newly presented claims, patentable over any applied references. The applicant’s or patent owner’s reply must appear throughout to be a bona fide attempt to advance the application or the reexamination proceeding to final action. A general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references does not comply with the requirements of this section. The reply must be reduced to writing (emphasis added)”, see 37 CFR 1.111 (b) & (c), M.P.E.P. 714.02.

Pointing out specific distinctions means clearly indicating in the written response what features/elements or distinctions have been added to the claim/claims, where support is found in the specification for such recitations and how these features are not shown, taught, obvious or inherent in the prior art.

If no amendments are made to claims as applicant or patent owner believes the claims are patentable without further modification, the reply must distinctly and specifically point out the supposed errors in the examiner’s action and must respond to every ground of objection and rejection in the prior Office Action in the same vain as given above, 37 CFR 1.111 (b) & (c), M.P.E.P. 714.02.


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The examiner also points out, due to the change in practice as affecting final rejections, older decisions on questions of prematurity of final rejection or admission of subsequent amendments do not necessarily reflect present practice. "Under present practice, second or any subsequent actions on the merits shall be final, except where the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c)" (emphasis mine), see MPEP 706.07(a).

**Conclusion**

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fidei whose telephone number is (571) 272-4553. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu can be reached on (571) 272-4562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
David T. Fidei  
Primary Examiner  
Art Unit 3728

dtf  
March 19, 2006